



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,661	05/26/2000	JEAN-PIERRE SACHETTO		6789

2292 7590 07/21/2003

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

GEORGE, KONATA M

ART UNIT PAPER NUMBER

1616

DATE MAILED: 07/21/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,661

Applicant(s)

SACHETTO ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 8-15, 22-30, 32, 33, 35-43 and 45-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 6, 15, 22, 24-26, 42, 43 and 45-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 10, 12-14, 28-30, 32, 33, 36, 37, 40 and 41 is/are rejected.
- 7) ☒ Claim(s) 9, 11, 23, 27, 35, 38 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1616

DETAILED ACTION

Claims 1-3, 6, 8-15, 22-30, 32, 33, 35-43 and 45-52 are pending in this application.

Election/Restrictions

1. Applicant elected to examine claims directed towards rectal administration, which are claims 8-14, 23, 27-30, 32, 33 and 35-41. Should the rectal composition be deemed to be allowable the remaining claims will be rejoined under the rejoinder rules and would also be allowed.

Action Summary

2. Claims 4, 31, 34 and 44 have been cancelled without prejudice or disclaimer.
3. The rejection of claims 1-4, 6, 15, 22-28 and 42-52 under 35 U.S.C. 103(a) over Savastano et al. is hereby withdrawn.
4. The rejection of claims 1-4, 6 and 22-28 under 35 U.S.C. 103(a) over Ulmius is hereby withdrawn.
5. The rejection of claims 1, 3, 6 and 22 under 35 U.S.C. 103(a) over Theeuwes et al. is hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1616

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 8, 10, 12, 13, 28-30, 32, 33, 36, 40 and 41 are rejected under 35

U.S.C. 102(b) as being anticipated by Slagel (WO 96/03115).

Slagel teaches a aqueous foamable composition comprising water, foaming agent, foam stabilizing and emulsifying surfactant and a water-soluble polymer (abstract). Page 3, lines 11-13 teach the composition used as for rectal or vaginal administration. Page 6, lines 31-36 also teach that when the composition is used for rectal administration the following clinical conditions can be treated with the composition, inflammatory bowel disease, irritable bowel syndrome and anorectal disorder. Page 6, lines 1-6 teach the water-soluble polymers as xanthan gum or hydroxypropyl methylcellulose and it used in concentrations of up to 5 weight percent. Table II, page 13 teaches a pharmaceutical composition comprising xanthan gum. It is taught in table II that xanthan gum is in a concentration of 2 g, which is 1.90 % w/w.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1616

7. Claims 8, 10, 12-14, 28-30, 32, 33, 36, 37, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slagel (WO 96/03115).

Slagel teaches a aqueous foamable composition comprising water, foaming agent, foam stabilizing and emulsifying surfactant and a water-soluble polymer (abstract). Page 3, lines 11-13 teach the composition used as for rectal or vaginal administration. Page 6, lines 31-36 also teach that when the composition is used for rectal administration the following clinical conditions can be treated with the composition, inflammatory bowel disease, irritable bowel syndrome and anorectal disorder. Page 6, lines 1-6 teach the water-soluble polymers as xanthan gum or hydroxypropyl methylcellulose and it used in concentrations of up to 5 weight percent. Table II, page 13 teaches a pharmaceutical composition comprising xanthan gum. It is taught in table II that xanthan gum is in a concentration of 2 g, which is 1.90 % w/w. Slagel does not disclose formulations comprising hydroxypropyl methylcellulose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use hydroxypropyl methylcellulose in the composition instead of xanthan gum as it is taught that both xanthan gum and hydroxypropyl methylcellulose can be used interchangeably in which either one can be employed.

Response to Arguments

8. Applicant's arguments with respect to claims 1-3, 6, 8-15, 22-30, 32, 33, 35-43 and 45-52 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1616

Allowabl Subject Matter

9. Claims 9, 11, 23, 27, 35, 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George



PATENT EXAMINER

A.U. 1616